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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,116	08/29/2003	Cheorl-Ho Kim	WON-FF-2002-US/P-113	1837

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,116	KIM ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Claims 1-4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 2-3 of claim 1, the phrase "the follicular fluid" lacks antecedent basis. On line 3 of claim 1, it is suggested to insert the phrase –collected from the human female—after the word "oocyte".

On line 2 of claim 3, it is suggested to change the phrase "wherein the diameter of the follicles selected is not less than 17mm" to –wherein the follicular fluid is collected from a follicle having a diameter not less than 17 mm—since claim 1 does not positively recite the follicles.

On line 2 of claim 4, the phrase "said follicle" lacks antecedent basis.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev et al.

Shalev et al teach of a method for measuring different matrix metalloproteinases, including matrix metalloproteinase-9 (MMP-9), in the follicular fluid of women undergoing induction of ovulation for in vitro fertilization. In the method, follicular fluid samples retrieved from the follicles of mature oocytes are collected from both women who undergo normal ovulation and women affected by polycystic ovarian syndrome (PCOS). Women who have PCOS are characterized by a degree of infertility. The follicular fluid samples are collected from follicles at least 18 mm in diameter. The level of MMP-9 in the follicular fluid samples is measured by substrate gel electrophoresis or zymography where the fluid samples are applied to a gel-containing gelatin as the substrate for MMP-9. Any MMP-9 in the samples serves to digest the gelatin in the gel. See page 326 in Shalev et al. Shalev et al teach that the level of MMP-9 in the follicular fluid of the women having PCOS is greater than in the women who undergo normal ovulation. See the results section on page 327 of Shalev et al. Shalev et al teach that it is known in the art that MMP-9 is present in the ovaries of humans, rats and mice, and this MMP allows

the development of ovarian follicles, the breakdown of the follicular wall to release a mature oocyte at the time of ovulation, and the formation of the corpus luteum from luteinizing follicular cells. See page 329 of Shalev et al. Shalev et al also teach that the high gelatinolytic activity by MMP-9 in the PCOS women could contribute to the rapid regression of the corpus luteum and consequently lead to insufficient luteal function for pregnancy to occur. See the first column on page 330 of Shalev et al.

Shalev et al fail to teach that the method for measuring MMP-9 in follicular fluid samples can be used to determine the probability of establishing pregnancy in a human female. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Shalev et al for such a purpose since Shalev et al teach that MMP-9 levels in fertile women differ from the levels found in infertile women, and also teach that MMP-9 contributes to the release of a mature oocyte from a follicle during ovulation, and in order for successful fertilization to occur, an oocyte must be released from a follicle for interaction with a sperm cell.

7. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev et al in view of the Molecular Probes brochure on the EnzChek Gelatinase/Collagenase assay kit (cited in the Office action mailed on July 29, 2004). For a teaching of Shalev et al, see previous paragraphs in this Office action. Shalev et al fail to teach of a kit for use in performing the method for measuring MMP-9 in follicular fluid samples.

The EnzChek Gelatinase/Collagenase Assay kit by Molecular Probes is used to measure the gelatinase or collagenase activity of matrix metalloproteinases (MMPs). The kit contains as

a component a protein substrate, which can be digested by an MMP. The protein substrate is gelatin, collagen I or collagen IV. See pages 1-2 of the brochure.

Based upon the combination of Shalev et al and the brochure on the EnzChek Gelatinase/Collagenase Assay kit by Molecular Probes, it would have been obvious to one of ordinary skill in the art to utilize the kit taught by the brochure for performing the method taught by Shalev et al since the method taught by Shalev et al involves zymography with a gelatin electrophoresis gel in order to measure the gelatinase activity of MMPs, and the kit in the brochure is also used to measure the gelatinase activity of MMPs. The kit taught by the brochure would allow the quick and efficient performance of the method taught by Shalev et al by having all of the reagents and other components needed to perform the method present in one place in the proper concentrations.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Riley et al and Lahav-Baratz et al who teach of methods for measuring MMP-9 and MMP-2 in follicular fluid samples.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

May 9, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700